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ROBERT J. HARTER 4233 CLIFFSIDE DRIVE LA CROSSE, WI 54601			EXAMINER NGUYEN, TRAN N	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/813,421

Applicant(s)

HARTER ET AL.

Examiner

Tran N. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Notice to Applicant***

1. This communication is in response to the communication filed 03/01/2007. The set of pending claims is as follows: 1, 3-33. The set of cancelled claim is as follows: 2.

***Response to Amendment***

2. In response to Applicant's amendment to claims 1, 32, and 33, the rejection under 35 U.S.C. 101 as imposed in the previous Office Action is hereby withdrawn.

It is noted that on page 11 Applicant argues that the magnitude value may be used internally; however, this limitation is not recited in the claim as originally presented, and devoid of this limitation, the claimed subject matter as a whole is nonstatutory.

3. In response to Applicant's amendment to claims 1, 8, 13, and 32, the rejection under 35 U.S.C. 112 2<sup>nd</sup> paragraph as imposed in the previous Office Action is hereby withdrawn.

It is noted that Examiner maintains the interpretation as originally adopted in the previous Office Action.

Applicant is thanked for the clarifications.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1, 3-4, 7, 12, and 14-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow (*The Merck Manual*) in view of Evans (*A Computer Assisted Management Program for Antibiotics and Other Antiinfective Agents*) (copies provided to Applicant in previous Office Action).

(A) As per claim 1, Applicant's admission of prior art indicates that skin tests and elimination diets are old and well established in the art (pages 2-3).

Berkow discloses a method of diagnosing patient allergy (pages 328-330) comprising:

- (a) identifying possible allergens (page 329 paragraph 6, page 330 Table 20-2);
- (b) identifying the reaction (page 329 paragraph 6);
- (c) identifying possible allergens the patient was exposed to during a first, second, and third period (page 329 paragraph 6, page 330 Table 20-2);
- (d) identifying symptoms during any period (page 329 paragraph 8);

(e) and calculating the correlation between symptoms and exposure to possible allergens (page 650 paragraph 4).

According to the teachings of Berkow, the method diagnoses a plurality of allergic reactions by attempting to correlate a plurality of symptoms exhibited by the patient to a plurality of possible allergens, e.g. foods, environmental exposure, etc.

Additionally, Berkow also teaches that the patient may be monitored for at least three weeks, each week on a different diet. This is evident because Diet 4 is intended to be applied when the first three diets have been exhausted with no improvement. Berkow also teaches that patterns of symptoms may be correlated to environmental exposure, including food, to diagnose an allergic reaction.

Berkow does not explicitly disclose the use of a computer to automate the method.

Evans discloses "a computerized decision-support program linked to computer-based patient records that can assist physicians in the use of antiinfective agents and improve the quality of care" (page 232 column 1 paragraph 1, page 234 column 1 paragraph 2, Table 1).

Evans also discloses that "[w]hen physicians select their own treatment plans, the computer automatically checks for allergies" (page 234 column 1 paragraph 3).

According to the teachings of Evans, the program is capable of linking patient record to assist therapeutic decisions, as well as enabling the physician to select and display data.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Evans in the method of Berkow with the motivation of providing patient data at the point-of-care (Evans; page 236 column 2 paragraph 1).

(B) As per claim 3, Berkow does not explicitly disclose that the correlation is sorted. Evans discloses that the program is capable of sorting data (page 233 Figure 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to sort data, as taught by Evans, when displaying data in the automatic allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of displaying data in an orderly manner as to quickly apprise the physician of the relevant information, as is evident from Evans (page 233 Figure 1).

(C) As per claim 4, Berkow discloses the addition of new possible allergens and monitoring for changes in symptoms (page 329 paragraph 8) (It is noted that new foods are considered "an additional possible influencing agent").

(D) As per claim 7, Berkow does not explicitly disclose entering additional symptoms; however, Berkow discloses monitoring the recrudescence of symptoms (page 329 paragraph 8).

Therefore, it would have been obvious to one ordinary skill in the art at the time of the invention to enter additional symptoms, i.e. reactions, as taught by Berkow, into

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the automated allergy diagnostic system as jointly taught by Berkow and Evans with the motivation of monitoring the recrudescence because this recrudescence is the best evidence of allergy (page 329 paragraph 8).

(E) As per claim 12, Berkow discloses that the clinical significance of a positive skin test "is determined when results are correlated with the pattern of symptoms and related to environmental exposures" (page 650 paragraph 4) (It is noted that the correlation represents the clinical significance of a positive skin test. Therefore, the correlation represents the likelihood that the agent in question is the allergen, and, as such, the likelihood that the agent may cause future reactions).

Berkow also discloses food abstinence to prevent future allergic reactions (page 329 paragraph 9) (It is noted that once the influencing agent, i.e. food, is identified, the patient should abstain from consuming such food in the future because it is likely that the food will cause a reaction when consumed).

(F) As per claim 14, Berkow discloses that the influencing agent may be foodstuff (pages 328-330).

(G) As per claim 15, Berkow discloses that ingredients in foods may cause reactions (page 329 paragraph 7).

(H) As per claim 16, Berkow discloses that the symptom occurs some time after the food is ingested (page 329 paragraph 6 and 8).

(I) As per claim 17, Berkow does not disclose assigning a confidence value to the correlation. Evans discloses determining 95 percent confidence interval (page 235 column 1 paragraph 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to calculate a confidence value for the regression, as taught by Evans, when implementing the automated allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of accurately determining the reliability of the calculated data when performing a study to determine the possible allergen (Evans; page 235 column 1 paragraph 1).

(J) As per claim 18, Berkow discloses that each period may be one day or more (page 329 paragraph 8, page 330 Table 20-2) (It is noted that Berkow intends for each elimination phase to last between a day and a week if the patient's symptoms are relieved; the patient's diet may also be changed daily, signifying the start of a new period of monitoring for symptoms).

(K) As per claim 19, Berkow discloses that "[c]ommonly incriminated food **allergens** include milk, eggs, shellfish..." (page 329 paragraph 7).



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(L) As per claim 20, Berkow discloses that the clinical significance is determined when skin test results are correlated with the pattern of symptoms and related to environmental exposures (page 650 paragraph 4).

(M) As per claim 21, Berkow discloses that “[e]osinophilic enteropathy, which may be related to specific food allergy, is an unusual illness with **pain**...” (page 328 paragraph 5) (It is noted that this symptom is a reaction with pain).

(N) As per claim 22, Berkow discloses that “[f]ood additives can produce... asthma” (page 329, paragraph 3) (It is noted that asthma is considered “respiratory-related”).

(O) As per claim 23, Berkow discloses that “perianal eczema have been attributed to food allergy” (page 328, paragraph 5) (It is noted that perianal eczema is considered “skin-related”).

(P) As per claim 24, Berkow discloses that “[e]osinophilic enteropathy, which may be related to specific food allergy, is an unusual illness with pain... that is associated with blood eosinophilia” (page 328, paragraph 5) (It is noted that blood eosinophilia is considered to be related to “blood pressure”).

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(Q) As per claim 25, Berkow discloses that the reaction is suboptimal athletic performance (page 328 paragraph 5) (It is noted that suboptimal athletic performance is considered "fatigue").

(R) As per claims 26 and 28, Berkow discloses that the reaction is depression (page 328 paragraph 5) (It is noted that depression is considered "mentally-related").

(S) As per claim 27, Berkow discloses that allergy could bring on anaphylaxis, a potentially fatal acute attack (page 330 paragraph 10). Berkow also discloses that patients who experience anaphylaxis may convulse and die (page 331 paragraph 3) (It is noted that convulsions are considered a form of "seizure").

(T) As per claim 29, Berkow discloses that smoking, i.e. exposure to cigarette smoke, may cause a reaction (page 650 paragraph 4).

6. Claims 5-6, 8, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow (The Merck Manual) in view of Evans (A Computer Assisted Management Program for Antibiotics and Other Antiinfective Agents) as applied to claim 1 above, and further in view of Rappaport (4,752,889).

(A) As per claim 5, neither Berkow or Evans discloses the use of a mouse to select data. Rappaport discloses selection by mouse-clicking (col. 4 lines 39-41, Figure 3B).

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At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Rappaport in the computerized allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of associating data items for displaying (Rappaport; col. 1 lines 65-67, col. 2, lines 34-38) (It is noted that "chunks" of knowledge are considered data items, according to Rappaport (see all Figures)).

(B) Claim 6 repeats the limitations of claim 5, and is therefore rejected for the same reasons, and incorporated herein. Particularly, the method as taught by Rappaport could be incorporated into the teachings of Berkow and Evans to provide quick and efficient selection of data items which represent the reactions.

(C) As per claim 8, neither Berkow or Evans discloses the displaying of the reaction and the possible influencing agents in a single view. Rappaport discloses that chunks may be displayed in the same view to facilitate selection (Figures 3A-3B).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to display data on a single screen to facilitate data selection, as taught by Rappaport, when implementing the automated allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of providing a global view of the knowledge base (Rappaport; col. 1 lines 65-67, col. 2 lines 34-38).

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(D) Claim 32 repeats the limitations of claims 1 and 4-6, cumulatively, and is therefore rejected for the same reasons, and incorporated herein.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow (*The Merck Manual*) in view of Evans (*A Computer Assisted Management Program for Antibiotics and Other Antiinfective Agents*) as applied to claim 1 above, and further in view of Kadtke (6,401,057).

(A) As per claim 9, neither Berkow or Evans discloses displaying the graph of the correlation versus time. Kadtke discloses graphing of a correlation parameter versus time delay (Figure 2B).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to generate and display the graph of the correlation versus time delay, as taught by Kadtke, when implementing the automated allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of providing efficient data detection (Kadtke; col. 1 lines 51-56) and estimating the deterministic properties of observed data (Kadtke; col. 1 lines 62-65).

8. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow (*The Merck Manual*) in view of Evans (*A Computer Assisted Management Program for Antibiotics and Other Antiinfective Agents*) as applied to claim 1 above, and further in view of Small (5,910,421).

(A) As per claim 10, neither Berkow or Evans discloses assigning a magnitude value to the reaction. Small teaches that magnitude values may be assigned to data points (Figure 2).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to assign magnitudes, as taught by Small, when implementing the automated allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of providing a method capable of distinguishing between allergies and infections (Small; column 6 line 10-12).

(B) As per claim 11, this claim is rejected for substantially the same rationale as applied to the rejection of claim 10, and incorporated herein.

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow (The Merck Manual) in view of Evans (A Computer Assisted Management Program for Antibiotics and Other Antiinfective Agents) as applied to claim 1 above, and further in view of Lowy (Medical Progress: Staphylococcus aureus Infections).

(A) As per claim 13, Berkow discloses that Toxic Shock Syndrome (TSS) is "almost always associated with menstruation" (page 88 paragraph 5); however, neither Berkow or Evans teaches that the patient's menstruation cycle is taken into account when diagnosing the allergy.

Lowy teaches that TSS may be caused by an allergic reaction to insect bite (page 527 column 2 paragraph 2).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to consider the menstruation cycle, as taught by Lowy, when implementing the automated allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of accurately diagnosing causes of TSS and thereby reducing patient deaths (page 527 col. 2 paragraph 2).

11. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow (*The Merck Manual*) in view of Evans (*A Computer Assisted Management Program for Antibiotics and Other Antiinfective Agents*) as applied to claim 1 above, and further in view of Mebane (5,486,999).

(A) As per claim 30, neither Berkow or Evans discloses that an amount of sleep the patient has may affect a reaction in the patient. Mebane teaches that the amount of sleep the patient has may be screened as factors that affect patient care (Appendix A, Questions 6 and 25).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to identify sleep as a possible influencing agent, as taught by Mebane, when implementing the automated allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of screening patients who improperly seek medical care for behavioral reasons (Mebane, col. 1 lines 18-21).

12. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow (*The Merck Manual*) in view of Evans (*A Computer Assisted Management Program for Antibiotics and Other Antiinfective Agents*) as applied to claim 1 above, and further in view of Teller (2002/0013538).

(A) As per claim 31, neither Berkow or Evans discloses downloading Internet accessible data that relates to environmental exposure and calculating a correlation between the exposure to patient symptoms.

Teller discloses downloading the pollen count from an Internet database in the same zip code as the patient and calculating the correlation thereof (page 3 paragraph 0040, page 6 paragraph 0074) (It is noted that pollen count is considered "data that relates to an environmental exposure").

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to correlate patient symptoms with locale-specific environmental data, as taught by Teller, when implementing the automated allergy diagnostic system, as jointly taught by Berkow and Evans, with the motivation of providing convenient and minimally intrusive, as well as dependable monitoring of health signs (Teller; page 1 paragraph 9 and 11).

13. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berkow (*The Merck Manual*) in view of Evans (*A Computer Assisted Management Program for*

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Antibiotics and Other Antiinfective Agents), Rappaport (4,752,889), Kadtko (6,401,057), and Small (5,910,421).

(A) Claim 33 repeats the limitations of claims 1, 3-6, 9-10, 12, and 14, cumulatively, and is therefore rejected for the same reasons, and incorporated herein.

### ***Response to Arguments***

14. Applicant's arguments filed 03/01/2007 have been fully considered but they are not persuasive.

(A) Setting all legal jargon aside, Applicant's invention is an automated system that correlates a set of challenges with a set of observed responses. Additionally, the system is capable of rudimentary data processing steps, including selecting, calculating, sorting, and displaying data.

Berkow discloses a plurality of substances capable of eliciting a plurality of allergic responses. Berkow also discloses that the cause of the response is confounded by many other variables to which the patient is exposed. The elimination diet is a method of minimizing confounding variables to the extent possible. Berkow also recognizes that some confounding is inevitable, as is evident by the various diets prescribed by Berkow to isolate and identify the cause, as well as the need to confirm positive challenges with double-blind administration of the challenge.



Evans discloses a computer system capable of rudimentary data processing with specific application towards identifying patient allergy.

(B) As per claim 1, on page 12 Applicant asserts that the invention of claim 1 has an advantage over the Berkow.

Claim 1 recites a method of correlating possible allergens with observed symptoms. While Applicant's asserted advantages may be true, the scope of the claim also envelops identifying the possible allergens as the results of the skin test, wherein a set of responses is correlated to a set of challenges. Therefore, the asserted advantage is moot with respect to at least some portions of the scope of claim 1.

(C) Applicant further argues that neither Berkow or Evans suggests Applicant's invention.

Berkow discloses that positive challenges need to be confirmed to establish statistical significance in a double-blind test (page 329 paragraph 6). The elimination diet is a challenge response test protocol wherein certain portions of the diet are control portions, other portions represent the challenge, and the patient is observed for the response, i.e. symptom. Berkow discloses a variety of diets for repeated use to establish statistical significance, as discussed in the section above.

Examiner respectfully maintains that an elimination diet as disclosed by Berkow suggests the method steps of correlating responses to challenges as recited by Applicant.

(D) Applicant further argues that elimination diets do not need to calculate a correlation. Applicant's argument is fully considered but is found to be not persuasive for the reasons discussed above. Berkow recognizes that positive challenges need to be confirmed in double-blind fashion in order to establish statistical significance.

While Examiner does not dispute Applicant's argument that Berkow discloses elimination diets, Examiner respectfully maintains that elimination diets fall within the scope of Applicant's claimed invention, and therefore the teachings of Berkow and Evans suggest the limitations of claim 1.

(E) Applicant further argues that Evans does not disclose identifying an unknown allergy. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Examiner respectfully maintains that Berkow and Evans in combination jointly teach the limitations of claim 1.

(F) Applicant further argues that Berkow discloses comparing skin prick test results with symptoms. Examiner does not dispute Applicant's observation, but nonetheless maintains that skin testing is a protocol of administering a series of challenges and then

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observing the test sites for the appropriate response. Berkow recognizes that positives need to be confirmed, as discussed above.

(G) As per claim 2, Applicant's argument on page 13 with respect to cancelled claim 2 is found to be not persuasive for the reasons stated above, and incorporated herein.

(H) As per claim 3, on page 13 Applicant argues that Evans does not disclose sorting data. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Examiner respectfully maintains that Berkow and Evans in combination jointly teach the limitations of claim 3.

(I) As per claim 4, on page 14 Applicant argues that some limitations of claim 4 is not necessarily "an influencing agent designated for a particular period". Examiner cannot attribute any reasonable interpretation to Applicant's argument. Additional clarification is requested.

(J) As per claim 7, on page 14 Applicant argues that monitoring the recrudescence of symptoms is not the same as entering a plurality of reactions.

Examiner maintains that monitoring recrudescence of symptoms is observing for the recrudescence of the response. Claim 7 recites entering the reaction. The reaction as recited by Applicant is the observed response. Therefore, Berkow discloses monitoring the recrudescence of the observed response to establish statistical significance of the challenge, as discussed above.

(K) As per claim 12, on page 14 Applicant argues that Berkow does not disclose "plurality of correlations" as recited by claim 12. Applicant also asserts that Applicant's invention does not need skin testing as compared to the cited references.

With respect to Applicant's asserted advantages, this argument is addressed above in the discussion of claim 1.

With respect to Applicant's argument, Examiner maintains that skin testing is a protocol of correlating challenges with observed responses to determine statistical significance, as discussed above.

(L) As per claim 14, on page 14 Applicant argues that Applicant is claiming a novel method capable of identifying food allergy.

Examiner maintains that Berkow and Evans jointly disclose a method capable of identifying allergy, including food allergy, as discussed above, and incorporated herein.

(M) As per claim 15, on page 14 Applicant argues that Berkow does not disclose "computing a correlation between the ingredient and the reaction".

Examiner maintains that Berkow and Evans jointly disclose a method capable of identifying allergy, including various ingredients contained in food, as discussed above, and incorporated herein. Specifically, Berkow discloses that it is not the food item itself, but the ingredients contained therein that represent the challenges capable of eliciting a response in the patient.

(N) As per claim 16, on page 14 Applicant argues that Berkow does not disclose "computing a time-delayed correlation".

Examiner maintains that Berkow discloses the possibility of a time delay between the challenge and the response, as is evident by the symptom occurring some time after ingestion. Examiner further maintains that this disclosure from Berkow in combination of the method as jointly disclosed by Berkow and Evans constitute a "time-delayed" correlation of challenges and responses.

(O) As per claim 17, on page 15 Applicant argues that Evans does not disclose calculating the confidence of a correlation value. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Specifically, Examiner maintains that Berkow discloses determining statistical significance between challenges as responses, as discussed in the discussion of claim

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1 above. Evans discloses that calculating confidence intervals to determine statistical significance is old and well established in the art of statistics. In combination, the cited art suggest the limitations of claim 17.

(P) As per claim 18, on page 15 Applicant asserts that the invention as claimed in claim 18 has certain advantages over Berkow.

Examiner respectfully maintains that Berkow discloses the limitations as recited in claim 18, and that the asserted advantages as argued by Applicant has been suggested by Berkow, as is evident by the fact that multiple diets are prescribed with the goal of identifying the positive challenge.

Additionally, it appears that Applicant's arguments are not directed towards any specific claim limitation. Additional clarification is requested.

(Q) As per claim 19, on page 15 Applicant argues that Berkow does not disclose identifying an allergen amongst "equally numerous" allergens. Applicant did not point out, or was Examiner able to find, any recitation of this limitation in claim 19.

Assuming *arguendo* that this limitation exists in claim 19, Examiner respectfully maintains that Berkow discloses a method of identifying the allergen from a myriad of possible allergens.

(R) As per claim 20, on page 15 Applicant argues that Berkow does not disclose identifying environmental exposure as the allergen.

Regardless of the fact that Berkow's method applies to skin test, the challenge administered to the patient represents allergens present as the result of environmental exposure. Correlating the challenge with the fact that the patient has previously experienced the same challenge-response pair creates statistical significance for the allergen in question.

Additionally, Berkow also discloses observing responses to food challenges, as discussed in the discussion of claim 1 above.

(S) As per claims 21-28, on page 15-16, Applicant argues that Berkow does not disclose identifying the allergens as recited in claims 21-29 as the possible allergen. Applicant admits that the recited allergens are well known to be the causes of allergic reactions.

Examiner respectfully maintains that the method as jointly disclosed by Berkow and Evans, and also in combination of the allergens as cited by Examiner and admitted by Applicant, is capable of identifying the recited allergens in claims 21-29.

(T) As per claim 29, on page 16 Applicant argues a newly added limitation not present in the claim as originally presented.

Examiner has changed the ground of rejection as necessitated by Applicant's amendment. It is noted that Examiner maintains that the interpretation adopted by Examiner, and upon which the original rejection was made, is consistent with the claim limitations as originally presented.

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(U) As per claim 5, on page 17 Applicant argues that neither Berkow or Evans provides motivation for the rejection of claim 5.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine can be found in Rappaport, which provides a convenient method of selecting displayed data.

(V) As per claim 6, on page 17 Applicant argues that neither Berkow or Evans suggests the step of selecting a reaction.

Examiner respectfully maintains that this limitation is substantially the same as the recited step in claim 5.

(W) As per claim 8, on page 17 Applicant argues that none of the cited references discloses displaying a single view as recited in claim 8.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections



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are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In particular, Rappaport discloses displaying data in a single view to facilitate selection (Figure 3A-3B). In combination with Berkow and Evans, Rappaport's disclosure anticipates Applicant's claim.

(X) As per claim 32, on page 17 Applicant argues that claim 32 should be allowed for the same reasons as claims 1, 2, and 4-6. Applicant states that claim 32 incorporates the limitations of cancelled claim 2.

In doing so, Applicant does not dispute Examiner's assertion that claim 32 repeats the limitations of claims 1 and 4-6. Since amended claim 1 is rejected, and since claim 1 incorporates all limitations of cancelled claim 2, it follows that claim 32 is rejected for the same rationale as applied to claims 1 and 4-6, and incorporated herein.

(Y) As per claim 9, on page 18 Applicant argues that claim 9 recites plotting the agent and reaction versus time, and that Kadtko fails to disclose this feature.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In particular, Kadtke's disclosure in combination with Berkow and Evans suggests the claimed invention.

(Z) As per claims 10-11, on page 18 Applicant argues that none of the recited references provide motivation for combining as applied to the rejection of claims 10-11.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation comes from Small to provide a method capable of distinguishing between allergies and infection (Small, col. 6 lines 10-12).

(AA) As per claim 13, on page 18 Applicant argues that the cited art does not recognize the problem where a menstrual period might alter a woman's usual reaction to an influencing agent, nor does the cited art suggest a solution in regards to claim 13.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., selectively considering or disregarding data collected during a menstrual cycle) are not recited in the rejected claim(s). Although the claims are interpreted in light of the

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Assuming *arguendo* that Applicant is correct that this limitation is present in the claim, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In particular, Berkow discloses that TSS is "almost always associated with menstruation" (page 88 paragraph 5). Lowy discloses that TSS may be caused by an allergic reaction to insect bite (page 527 column 2 paragraph 2).

In combination, the cited art suggests that menstruation affects a patient's response, and if the cause is confounded, the improper treatment arising therefrom may cause patient death (Lowy; page 527 column 2 paragraph 2).

(AB) As per claim 30, on page 19 Applicant argues that Applicant is not claiming that the amount of sleep the patient has may be screened as factors that affect patient care in claim 30.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

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USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In particular, claim 30 recites that the method may operate to identify the amount of sleep of the individual as a possible cause. Mebane discloses that the amount of sleep in a patient is a possible cause of reactions in a patient, and may not warrant clinical treatment. In combination, the cited art disclose the claim limitations.

(AC) As per claim 31, on page 19 Applicant disagrees with the rejection of claim 31; however, Applicant did not specifically point out which limitation of the claim was inadequately addressed by the rejection.

Additionally, Applicant's amendment to the claim does not put the claim in condition for allowance for the following reason. The cited art in combination suggest that environmental data may be updated from remote databases to identify the cause of the allergic reaction by correlating the patient's exposure to the information obtained from the databases.

(AD) As per claim 33, on page 20 Applicant argues that claim 33 should be allowed for the same reasons as claims 1-6, 9, 10, 12, and 14. Applicant states that claim 33 incorporates the limitations of cancelled claim 2.

In doing so, Applicant does not dispute Examiner's assertion that claim 32 repeats the limitations of claims 1, 3-6, 9, 10, 12 and 14. Since amended claim 1 is rejected, and since claim 1 incorporates all limitations of cancelled claim 2, it follows

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that claim 33 is rejected for the same rationale as applied to claims 1, 3-6, 9, 10, 12 and 14, and incorporated herein.

### **Conclusion**

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Bates (Improving Safety with Information Technology, 2003) discloses the use of computers to aid physicians, e.g. neural networks (page 2529).

Tepper (6,756,032) discloses a method of identifying an allergen via a challenge-response protocol to identify the allergen (Abstract).

Waite (4,414,629) discloses a method to calculate cause-effect correlation for a set of observed data, wherein the method is particularly suited for etiology (column 26 line 31-34).

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from Examiner should be directed to Tran N. Nguyen (Ken) whose telephone number is (571) 270-1310. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:00 pm, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, Examiner's Supervisor, Joseph Thomas can be reached on (571) 272-6776.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TN   
4/20/2007

  
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